

# POLICY AND COMMUNICATIONS BULLETIN

## THE CLINICAL CENTER

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Medical Administrative Series

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M86-5 (del.)

4 October 2000

### MANUAL TRANSMITTAL SHEET

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SUBJECT: Phlebotomy in NIH Intramural Laboratory  
Research Activities

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1. Explanation of Material Transmitted: This issuance directs the deletion of this policy from the Medical Administrative Series, because it is outdated, and because all human blood obtained for research is subject to the same provisions in 45 CFR 46, the human subject protection regulations.
2. Material Superseded: No. 86-5, dated May 12, 1986
3. Filing Instructions: Informed Consent Section

Remove: No. 86-5, dated May 12, 1986

Insert: None

### DISTRIBUTION

Physicians and Dentists Participating in Patient Care  
CC Department Heads and Office Chiefs  
Institute Clinical Directors

# POLICY AND COMMUNICATIONS BULLETIN

## THE CLINICAL CENTER

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Medical Administrative Series

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M 86-5 (del.)

**DELETED**

SUBJECT: Phlebotomy in NIH Intramural Laboratory  
Research Activities

### PURPOSE

Department of Health and Human Services (HHS) regulations on the protection of human subjects of research apply to all research "conducted by Department employees" [45 CFR 46.101 (1)]. The Assurance of the Clinical Center (CC), NIH, to the Secretary, HHS, states that the intramural programs comply with these regulations [45 CFR 46.103 (a)].

Researchers routinely require small amounts of blood for controls or specimens in laboratory research. The volunteer for phlebotomy in such instances is often a co-worker. To protect these subjects of research and to assure that incidental phlebotomy is carried out within the scope of HHS regulations, the CC Medical Board has adopted and the Director, CC, has approved the following policy, which was recommended by the NIH Human Research Review Panel (HRRP) [later renamed the Human Subjects Research Advisory Committee (HSRAC)].

### POLICY

1. Each Institute Clinical Director shall designate one or more phlebotomists who shall perform venipuncture to obtain blood for laboratory research if the researcher is not an M.D. or otherwise experienced phlebotomist.

2. For safety and protection in case of vasovagal reaction, the subject shall be seated for the procedure in a chair with back and arms.
3. Verbal consent for the procedure shall be obtained. Written consent is not required with the HSRAC finds that "the research presents no more than minimal risk...and involved no procedures for which written consent is normally required outside of the research context" [45 CFR 46.117 (2)].